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10/657,915	09/09/2003	Kenneth M. Adams	M190.145.101	7670

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EXAMINER

HOFFMAN, MARY C

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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10/05/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/657,915	Applicant(s) ADAMS ET AL.	
	Examiner MARY HOFFMAN	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03/03/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15-24 and 31-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-24 and 31-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

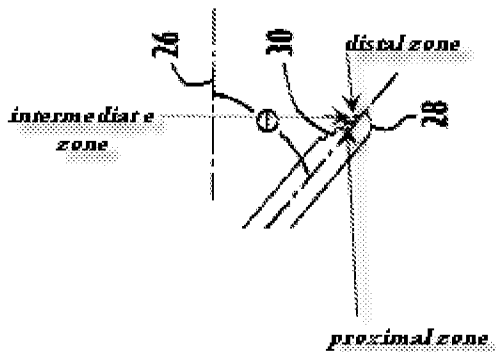
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10, 13, 15-20, 22-23, 31-32 and 34-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Anctil et al. (U.S. Patent No. 5,922,003) (“Anctil”).

Anctil discloses a surgical micro-burring instrument comprising an outer tubular member (see FIG. 20) having a proximal section (712), an intermediate section (718), a distal section (724), and a central lumen extending from the proximal section to the distal section, the distal section forming: a pocket (730, serrated window, col. 12, line 37, see below marked up figure) fluidly connected to the central lumen, the pocket having a bottom surface and an opposed upper opening, an elevator tip (distal-end of device) extending distal the pocket, a proximal portion proximal the pocket, the proximal portion forming a tube, wherein the pocket is defined by a side wall having an upper edge including a proximal zone extending from the proximal portion, an intermediate zone extending from the proximal zone, and a distal zone extending from the intermediate zone to a distal-most end of the pocket at which the central lumen terminates, and further wherein relative to an orientation of the outer tubular member in which the bottom surface is the lowest-most surface of the pocket: the proximal zone

extends downwardly from the proximal portion toward the bottom surface, the intermediate zone extends from the proximal zone at an angle of extension relative to the proximal zone that differs from an angle of extension of the proximal zone relative to the proximal portion, the distal zone extends downwardly from the intermediate zone toward the bottom surface at an angle of extension differing from the angle of extension of the intermediate zone relative to the proximal zone; and an inner tubular member rotatably received within the central lumen, a distal end of the inner tubular member forming a bur positioned within the pocket, such that upon final assembly, at least a portion of the bur is exposed relative to the outer tubular member via the upper opening of the pocket.



The proximal zone extends from the proximal portion in an angularly downward fashion. The intermediate zone is parallel with a central axis of the proximal portion. The bottom surface forms at least one opening fluidly connected to an irrigation source. An irrigation tube (790) extending exteriorly along the outer tubular member and fluidly connected to the at least one opening. Upon final assembly, a distal end of the bur is longitudinally spaced from the distal-most end point. An aspiration passage extending through the outer tubular member for aspirating cut tissue. The inner tubular member

Art Unit: 3733

forms a lumen defining the aspiration passage (748) with the bur forming an opening at a distal end thereof, and further wherein the opening is in fluid communication with the lumen of the inner tubular member. The intermediate section of the outer tubular member defines a longitudinal bend. The bur forms a plurality of cutting flutes (see FIG. 23). The bur has a shape selected from the group consisting of cylindrical, spherical, hemispherical, ellipsoidal, and pear. The bottom surface forms a plurality of ports opposite the upper opening (792). The distal end opening formed by the bur is in an axial opening, and further wherein the upper edge is shaped such that when the bur is in a distal-most position relative to the distal-most end of the pocket, the opening is unobstructed by the outer tubular member. The bur is configured to remove hard bone with rotation of the inner tubular member. The instrument is adapted for use in a septoplasty procedure. The elevator tip is selectively axially moveable relative to the bur.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anctil et al. (U.S. Patent No. 5,922,003).

Art Unit: 3733

Ancil discloses the claimed invention except for the longitudinal bend of the intermediate section being approximately 12° relative to a central axis defined by the proximal section.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the longitudinal bend of the intermediate section of Ancil being approximately 12° relative to a central axis defined by the proximal section, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claims 2-9, 11-12 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ancil et al. (U.S. Patent No. 5,922,003) in view of Adams (6,503,263).

Ancil discloses the claimed invention except for the elevator tip including an upper surface extending from the distal-most end of the pocket, the upper surface including a proximal region and a distal region, wherein at least a portion of the distal region extends from the proximal region in an angular fashion in longitudinal cross-section, wherein at least a portion of the proximal region of the upper surface of the elevator tip extends downwardly from the distal-most end of the pocket, wherein the proximal region is curved in longitudinal cross-section, wherein the elevator tip terminates in a distal end point, and further wherein the distal end point is laterally above the distal-most end of the pocket when the outer tubular member is oriented such that the bottom surface of the pocket is below the upper opening, wherein the distal-

Art Unit: 3733

most end is below a central axis of the central lumen when the outer tubular member is spatially oriented such that the bottom surface is a lowest-most surface of the pocket, which distally extends at least 0.05 inch relative to the distal-most end of the pocket, the angular extension of the distal region defines an included angle in the range of 10° - 50° relative to a central axis of the outer tubular member, the included angle is approximately 20° , the included angle is approximately 40° , wherein angular extension of the proximal zone defines an included angle in the range of 100° - 140° relative to a central axis of the proximal portion, wherein the included angle is approximately 120° .

Adams discloses elevator tip including an upper surface extending from the distal-most end of the pocket, the upper surface including a proximal region and a distal region, wherein at least a portion of the distal region extends from the proximal region in an angular fashion in longitudinal cross-section, wherein at least a portion of the proximal region of the upper surface of the elevator tip extends downwardly from the distal-most end of the pocket, wherein the proximal region is curved in longitudinal cross-section, wherein the elevator tip terminates in a distal end point, and further wherein the distal end point is laterally above the distal-most end of the pocket when the outer tubular member is oriented such that the bottom surface of the pocket is below the upper opening, wherein the distal-most end is below a central axis of the central lumen when the outer tubular member is spatially oriented such that the bottom surface is a lowest-most surface of the pocket, in order to provide improve tissue dissecting of the device.

Art Unit: 3733

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the elevator tip of Anctil including an upper surface extending from the distal-most end of the pocket, the upper surface including a proximal region and a distal region, wherein at least a portion of the distal region extends from the proximal region in an angular fashion in longitudinal cross-section, wherein at least a portion of the proximal region of the upper surface of the elevator tip extends downwardly from the distal-most end of the pocket, wherein the proximal region is curved in longitudinal cross-section, wherein the elevator tip terminates in a distal end point, and further wherein the distal end point is laterally above the distal-most end of the pocket when the outer tubular member is oriented such that the bottom surface of the pocket is below the upper opening, wherein the distal-most end is below a central axis of the central lumen when the outer tubular member is spatially oriented such that the bottom surface is a lowest-most surface of the pocket, in view of Adams in order to provide improve tissue dissecting of the device.

It would have been further obvious to one having ordinary skill in the art at the time the invention was made to construct the elevator tip of Anctil wherein which distally extends at least 0.05 inch relative to the distal-most end of the pocket, the angular extension of the distal region defines an included angle in the range of 10° - 50° relative to a central axis of the outer tubular member, the included angle is approximately 20° , the included angle is approximately 40° , wherein angular extension of the proximal zone defines an included angle in the range of 100° - 140° relative to a central axis of the proximal portion, wherein the included angle is approximately 120° , since it has been

Art Unit: 3733

held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anctil et al. (U.S. Patent No. 5,922,003) in view of view of West, Jr. (U.S. Patent No. 5,364,395).

Anctil discloses the claimed invention except for an intermediate tubular member co-axially disposed between the inner tubular member and the outer tubular member, the intermediate tubular member forming a distal window through which at least a portion of the bur is exposed; wherein the outer tubular member is slidably received over the intermediate tubular member.

West, Jr. discloses an intermediate tubular (ref. #92) member co-axially disposed between the inner tubular member and the outer tubular member, the intermediate tubular member forming a distal window through which at least a portion of the bur is exposed; wherein the outer tubular member is slidably received over the intermediate tubular member in order to provide an electrically insulative layer (col. 9, lines 55-67).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Anctil with an intermediate tubular member co-axially disposed between the inner tubular member and the outer tubular member, the intermediate tubular member forming a distal window through which at least a portion of the bur is exposed; wherein the outer tubular member is slidably received over the intermediate tubular member in view of West, Jr. in order to provide

Art Unit: 3733

an electrically insulative layer.

Response to Arguments

Applicant's arguments filed 06/03/2009 have been fully considered but they are not persuasive.

Applicant argues that Anctil does not disclose 1) the claimed proximal, intermediate, and distal zones, and 2) an elevator tip in the claimed "elevated fashion".

Regarding Applicant's first argument, the term zone can be interpreted broadly. The "arbitrary" zones pointed out by the examiner meet the claim limitations because the zones are positioned proximal, intermediate, and distal as claimed.

Regarding Applicant's second argument, the term "elevator tip" can be interpreted broadly. The tip of the Anctil reference can facilitate lifting or elevation of tissue (see page 16, line 15, of Applicant's specification), and therefore can be considered an elevator tip.

The rejections are deemed proper.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

Art Unit: 3733

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARY HOFFMAN whose telephone number is (571)272-5566. The examiner can normally be reached on Monday-Thursday 10:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/657,915

Page 11

Art Unit: 3733

/Mary C. Hoffman/

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733